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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,638	01/29/2004	Paul S. Charifson	VPI/02-128 US	5416

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VERTEX PHARMACEUTICALS INC.
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EXAMINER	
CHANG, CELIA C	
ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
11/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,638	CHARIFSON ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 28-32* is/are pending in the application.

4a) Of the above claim(s) *22-25,30 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-21,26,28,29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants dated Aug. 22, 2007 and a declaration under 37 CFR 1.132 were filed and been entered and considered carefully.

Claim 27 have been canceled. Claims 22-25, 30-31 stayed withdrawn. Claims 1-21, 26, 28-29 and newly added 32 are pending.

2. The rejection of claims 26-27 under 35 USC 112 second paragraph is maintained for claim 26 (claim 27 has been canceled) for reason of record.

Applicants' arguments further support the indefiniteness of the "scope" of the claims. As it has been clearly delineated in the previous office action, decreasing bacterial quantity does not necessarily meet the utility requirement. As it is evidenced by the article by the American Institute of Biological Sciences, the concept of "all bacterial are bad for you" is erroneous. In addition, the claimed compounds, as evidenced by the 132 Declaration, is limited to efficacy of three gram positive bacteria. If the "patient" of claim 26 has an increased population of gram negative bacteria, the compounds would have no utility for such scope.

The rejection for "preventing a bacterial infection in a patient" of claim 27 is now applicable to claim 32. Again, who is the "patient"? If the patient has been infected with organisms: Streptococcus pneumoniae, Streptococcus pyogenes, Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus, Coag. Neg. Staph, Bacillus anthracis, or Staphylococcus epidermidis, then the de novo prevention cannot exist, the scope of the claim is self conflicting. If the patient is not infected with the above bacteria, then, who is the patient?

3. The rejection of claims 26, 28-29, under 35 USC 112 first paragraph is maintained for reason of record and now also applicable to newly added claim 32.

Please note that the support of the 132 declaration is limited to efficacy of the claimed compounds against *S. aureus, E. faecalis or S. pneumoniae*. Therefore, if a person is infected with the three bacteria, the administration of the compounds is enabled in treating or decreasing the infection of these bacteria. Nowhere can the scope of treating "all patients", irrespective of

what the pathological basis for a patient can be, with the claimed compounds can achieve treatment or decrease severity of infection.

Please note that administration of antibiotics is not always beneficial (see MayClinic, Americal instituteof biological sciences). Especially, applicants' allegation that in preventing post operative or opportunistic infections, *a strickly gram positive* antibiotics is given to prevent post operative or opportunistic infection is lacking.

In addition, the Webster dictionary is provided for applicants' convenience showing that the term "prevention" given the broadest interpretation including "ward-off of all infection" which is incredible. Ward-off means zero occurrence. Even vaccines could not give such degree of "prevention". Applicants provided no factual support that the compounds, if given to post operative surgical patients, would give zero occurrence in infection of organisms: Streptococcus pneumoniae, Streptococcus pyogenes, Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus, Coag. Neg. Staph, Bacillus anthracis, or Staphylococcus epidermidis.

4. The provisional obviousness type double patenting over claims 1-21, 26, 28-29, now applicable to claim 32, over pending claims of SN 10/459,420 is dropped in view of the amendments. However, the rejection if now applicable over the issued patent or copending claims as recited on the newly provided PTO-1449.

Claims 1-21, 26, 28-29, 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 19-22 of U.S. Patent No. 6,632,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant scope fully embraced the issued scope when the compounds are drawn to issued formula IIa. Please note that generically, all R1, R2 and R3 can be optionally substituted heteroaryl or heterocycle, therefore, the instant claims, genus and species are generically embraced by the issued claims. The wherein the issued species claims of di-heteorcylic moieties susbstituted compounds (see for example #164, 178 etc.) are position isomers of the instant claims. Position isomerism for the same utility has long been recognized by the court being structurally prima facie. (See In re Mehta 146 USPQ 284, Ex parte Engelhardt 208 USPQ 343, In re Dillon 16 USPQ2d 1897, 1911).

Claims 1-21, 26, 28-29, 32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the pending claims of copending cases SN 10/444,588; 10/833,995; 10/901,928; 10/971,573; 10/986,569; alone or in view of US 6,632,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because overlapping scope are found in the copending claims which rendered the remaining Markush variation prima facie over each other. Please note that generically, all R1, R2 and R3 can be optionally substituted heteroaryl or heterocycle, therefore, the instant claims, genus and species are generically embraced by the copending claims, while the species of each copending claims are rendered obvious by the generic teaching of mix and match in substitutents or positions of the broad teaching by the issued or copending generic claims.

Applicants are requested to provide pending scope which can be shown to be clearly demarcated from the instant scope or file appropriate terminal disclaimer.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Applicants amendments necessitated the new grounds of rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Oct. 29, 2007

Celia Chang
Primary Examiner
Art Unit 1625